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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/640,853

08/13/2003

Randall V. Sparer

P-10998.00

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7590

01/22/2010

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EXAMINER

ROGERS, JAMES WILLIAM

ART UNIT

PAPER NUMBER

1618

MAIL DATE

DELIVERY MODE

01/22/2010

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/640,853	<b>Applicant(s)</b> SPARER ET AL.	
	<b>Examiner</b> JAMES W. ROGERS	<b>Art Unit</b> 1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 01 December 2009.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 89-150 is/are pending in the application.
- 4a) Of the above claim(s) 90,92,105-133 and 139 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 89,91,93-104,134-138 and 140-150 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>11/30/2009, 12/01/2009</u> . | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

Applicants amendments to the claims filed 12/01/2009 have been entered.

Applicants have cancelled claims 1-88 and added new claims 89-150.

#### ***Continued Examination Under 37 CFR 1.114***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 12/01/2009 has been entered.

#### ***Election/Restrictions***

This application contains claims directed to the following patentably distinct species the various types of 1<sup>st</sup> and 2<sup>nd</sup> polymers in the miscible polymer blend. The species are independent or distinct because claims to the different species recite the mutually exclusive characteristics of such species. In addition, these species are not obvious variants of each other based on the current record.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 89-150 are generic.

There is an examination and search burden for these patentably distinct species due to their mutually exclusive characteristics. The species require a different field of search (e.g., searching different classes/subclasses or electronic resources, or

Art Unit: 1618

employing different search queries); and/or the prior art applicable to one species would not likely be applicable to another species; and/or the species are likely to raise different non-prior art issues under 35 U.S.C. 101 and/or 35 U.S.C. 112, first paragraph.

**Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species to be examined** even though the requirement may be traversed (37 CFR 1.143) **and (ii) identification of the claims encompassing the elected species**, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

The election of the species may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the election of species requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, applicant must indicate which of these claims are readable on the elected species.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the species unpatentable over the

Art Unit: 1618

prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other species.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141.

During a telephone conversation with Anne Mueeting on 12/16/2009 a provisional election was made with traverse to prosecute the species of polyurethane and polyphenylene oxide, claims 89,91,93-104,134-138 and 140-150 read on the elected species. Affirmation of this election must be made by applicant in replying to this Office action. Claims 90,92 ,105-133 and 139 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 89,91,93-104,134-138 and 140-150 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Specifically independent claims 89 and 134 recite "miscible polymer blend that controls delivery of the active agent at a predetermined amount over a period of time", the examiner could

Art Unit: 1618

not find support for this new recitation nor have applicants led the examiner to where such support within the specification could be found. The examiner could not even find a recitation of the word "predetermined" within applicant's specification.

***Claim Rejections - 35 USC § 102***

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

***Response to Arguments***

**Claims 89,91,93-104,134-138 and 140-150 are rejected under 35 U.S.C. 102(b) as being unpatentable by Hossainy et al. (US 6,153,252), for the reasons set forth in the previous office action filed 09/11/2008 and 08/25/2009.**

**Claims 89,91,93-104,134-138 and 140-150 are rejected under 35 U.S.C. 102(b) as being unpatentable by Whitbourne et al. (US 6,110,483), for the reasons set forth in the previous office action filed 09/11/2008 and 08/25/2009.**

**Claims 89,91,93-104,134-138 and 140-150 are rejected under 35 U.S.C. 102(e) as being anticipated by Sirhan et al. (US 2002/0082679 A1), for the reasons set forth in the previous office action filed 09/11/2008 and 08/25/2009.**

It is noted by the examiner that the above references are silent in regards to the elected species of polyphenylene oxide, but since this species is not claimed separately the previous rejection still stand over the amended claims. The new claim set differ from previous claim set by incorporating the recitation of "method of tuning the delivery of an active agent" and the recitation of "implantable medical implant" in the preamble, the

Art Unit: 1618

recitation on methods of determining the solubility parameters, and the delivery of the active at a predetermined amount over a period of time which is not controlled by porosity. These new recitations do not exclude the reasoning for the old rejections over Hossainey, Whitbourne and Sirhan set forth in the previous office actions filed 09/11/2008 and 08/25/2009 and for the reasons set forth below in the response to arguments, therefore the previous prior art rejections are applied to new claims 89,91,93-104,134-138 and 140-150.

Applicant's arguments filed 12/01/2009 have been fully considered but they are not persuasive.

Applicants assert there is no teaching or suggestion in Sirhan, Whitbourne or Hossainey on tuning the delivery of an active agent from an implantable medical device to a subject using a miscible polymer blend with the recited relationships of solubility parameters of the polymers and active at a predetermined amount over a period of time not controlled by porosity.

The examiner notes the above argument but does not find it persuasive. The claimed method of tuning the delivery of an active agent recites the same steps of forming a polymer blend with the recited relationships of solubility parameters of the polymers and active found in previous claim sets. Since the implants described by Hossainey, Whitbourne and Sirhan teach the same types of polymer blends and active agents it is inherent that the same composition will have the same the same properties including its ability of "tuning" the active agent, the claimed solubility parameter relationships and the release of the active. To meet the claimed method the examiner

Art Unit: 1618

conducted his search based upon the active steps recited within the claims, that is a method of receiving a first and second polymer as claimed in combination with the claimed active to form an implantable device. The recited "tuning the delivery of the active" was seen as being met if all of the active steps recited in the claim body were met. The subject matter of a properly construed claim is defined by the terms that limit its scope. It is this subject matter that must be examined. As a general matter, the grammar and intended meaning of terms used in a claim will dictate whether the language limits the claim scope. Language that suggests or makes optional but does not require steps to be performed or does not limit a claim to a particular structure does not limit the scope of a claim or claim limitation.

Applicants assert that the references above teach several different classes of polymers, thus applicants surmise that the references each specify a vast number of individual polymer species. Applicants further contend that there is no guidance within the references above to select the same polymer blend claimed by applicants with the recited relationships of solubility parameters.

Firstly with respect to Sirhan the polymer blend described is claimed, all US patents are considered valid thus, there is adequate guidance and direction for the claimed polymers. As mentioned numerous times in actions in the past and again herein both the Hossainey and Whitbourne references clearly teach the same first and second polymers claimed by applicants. Whitbourne claims polyvinyl acetals and acetates, acrylic polymers, methacrylic polymers meeting applicants claimed second polymer and also claims an active agent that included several cellulose derivatives and



Art Unit: 1618

polyurethanes as detailed within the disclosure of the specification. Hossainey claims several cellulose derivatives within the claims and the description of the specification list polyamides, polyesters, polymethacrylates polyolefins, and ethylene methyl methacrylate copolymers as useful ingredients in the polymer film. Thus from the claimed invention of Whitbourne and Hossainey and the descriptions of other polymers that are useful within their respective specifications one of ordinary skill in the art would have readily envisaged from the teachings of Whitbourne and Hossainey applicants claimed drug delivering polymer blend and the method to produce it. Also in regards to Whitbourne and Hossainey, the prior art's mere disclosure of more than one alternative does not constitute a teaching away from any of these alternatives because such disclosure does not criticize, discredit, or otherwise discourage the solution claimed. Furthermore while both the references above teach and claim numerous polymer blends, this only supports the fact that polymer blends are a well known and very mature field. One of ordinary skill in the art would know from the teachings of the references and what is generally well known and established in the art that numerous polymers can be blended or mixed together to form coatings for medical devices. In the same regard applicants specification and claims are also broad in the number of types of polymers that can be blended, but the examiner has concluded that applicants have provided enough written description and showed enablement since the field of polymer blends is well known and very mature field, thus there are currently no 112 1<sup>st</sup> paragraph rejections over the breadth of the claims. However applicants argue that a prior art reference which is similar to their claimed invention in that it also describes

Art Unit: 1618

numerous types of polymer blends, does not teach their claimed blend just because numerous combinations are possible. A lack of adequate written description issue arises if the knowledge and level of skill in the art would not permit one skilled in the art to immediately envisage the product claimed from the disclosed process. As detailed above the examiner concluded from the prior art that polymer blends used as coatings for medical articles is a very mature field, thus the breadth of the number of possible combinations would not preclude one of ordinary skill in the art from envisioning nearly any combination of polymers that are described as being capable of being blended. Thus the examiner believes there is adequate support and guidance within each reference so that one of ordinary skill in the art would have readily envisaged applicants claimed invention from the teachings of Hossainey and Whitbourne.

Claims 89,91,93-97,99,101-103,134-138 and 140-141,143,145,147-150 are rejected under 35 U.S.C. 102(e) as being anticipated by Atala (US 6,576,019).

Atala teaches biocompatible synthetic or natural polymeric matrixes for tissue reconstruction. See abstract and claims. The polymeric matrix could be formed from materials in which both polyurethane and polyphenylene oxide could be selected as a blend. See claim 3. The polymeric matrix itself could be treated with additives or drugs prior to implantation to promote the formation of new tissue. See col 7 lin 58-col 8 lin 20. Regarding the selection of the first and second polymer and active ingredient based upon their solubility parameters being no greater than a the range  $3 \text{ J}^{1/2} \text{ cm}^{3/2}$ , Atala teaches the mixtures of the same polymers and active ingredients as applicants claimed invention, therefore it is inherent that the same polymers and active ingredients will

Art Unit: 1618

have the same solubility parameters. It appears as though applicants are claiming a new and/or undiscovered property of an old composition. Where the claimed and prior art products are identical or substantially identical in structure or composition, or are produced by identical or substantially identical processes, a prima facie case of either anticipation or obviousness has been established. Thus the claiming of a new use, new function or unknown property which is inherently present in the prior art does not necessarily make the claim patentable.

***Claim Rejections - 35 USC § 103***

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

**Claims 89,91,93-104,134-138 and 140-150 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sirhan et al. (US 2002/0082679 A1), in view of Van Krevelen, Properties of Polymers, Chapter 7, 3<sup>rd</sup> ed., Elsevier., for the reasons set forth in the previous office action filed 08/25/2009.**

**Claims 89,91,93-104,134-138 and 140-150 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sirhan et al. (US 2002/0082679 A1), in view of in view of Coleman et al., Specific interactions and the miscibility of polymer blends, Ch 2, a practical guide to polymer miscibility pages 49-156, for the reasons set forth in the previous office action filed 09/11/2008.**

**Claims 89,91,93-104,134-138 and 140-150 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hossainy et al. (US 6,153,252), in view of Van**

**Krevelen, Properties of Polymers, Chapter 7, 3<sup>rd</sup> ed., Elsevier, for the reasons set forth in the previous office action filed 09/11/2008.**

**Claims 89,91,93-104,134-138 and 140-150 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hossainy et al. (US 6,153,252), in view of in view of Coleman et al., Specific interactions and the miscibility of polymer blends, Ch 2, a practical guide to polymer miscibility pages 49-156, for the reasons set forth in the previous office action filed 09/11/2008.**

**Claims 89,91,93-104,134-138 and 140-150 are rejected under 35 U.S.C. 103(a) as being unpatentable over Whitbourne et al. (US 6,110,483), in view of Van Krevelen, Properties of Polymers, Chapter 7, 3<sup>rd</sup> ed, for the reasons set forth in the previous office action filed 09/11/2008.**

**Claims 89,91,93-104,134-138 and 140-150 are rejected under 35 U.S.C. 103(a) as being unpatentable over Whitbourne et al. (US 6,110,483), in view of in view of Coleman et al., Specific interactions and the miscibility of polymer blends, Ch 2, a practical guide to polymer miscibility pages 49-156, for the reasons set forth in the previous office action filed 09/11/2008.**

### ***Response to Arguments***

As in their remarks above applicants contend that there is no teaching or suggestion in Hossainey, Whitbourne or Sirhan on tuning the delivery of an active agent from an implantable medical device to a subject using a miscible polymer blend with the recited relationships of solubility parameters of the polymers and active at a predetermined amount over a period of time not controlled by porosity.

The examiner for the reasons set forth above respectfully disagrees.

Applicants further contend in regards to claims 102 and 148 that the cited references do not describe how delivery of the active occurs predominantly under permeation control.

Once again the examiner relies on the fact that the reference describes the same type of composition therefore any claimed properties of that composition are met including delivery of the active. A composition and its properties are inseparable.

Lastly applicants assert that the references above do not provide a teaching or suggestion that would direct one of ordinary skill in the art to select applicants claimed subset of polymer and active agent combinations from the innumerable combinations described within each. Applicants purport the case law of KSR International Co. v. Teleflex Inc. (KSR), 550 U.S. \_\_\_, 82 USPQ2d 1385 (2007) and Sud-Chemie, inc v. Multisorb Technologies support their contention that while the references above describe classes of polymers that may be blended it is taken from innumerable species that have different properties including solubility parameters and without guidance for this selection the combinations above cannot render applicants claims obvious.

The examiner respectfully disagrees. While the examiner notes the case law provided above the current issue differs from the specific cases cited above. The examiner relies on his remarks above regarding Hossainy, Whitbourne and Sirhan as to why one of ordinary skill in the art could have readily envisaged or been obvious to select the claimed blend. Regardless applicant's remarks seem to only point out that guidance is not provided in the primary reference when clearly the rejections were made

Art Unit: 1618

in combination with the secondary references Van Krevelen or Coleman. Clearly as set forth in the previous office action the primary references above are silent in regards to solubility parameters, however both Van Krevelen and Coleman describe how to calculate solubility parameters and use them to predict miscibility. Both Van Krevelen and Coleman describe that when two polymers are close in their solubility parameter the greater the likelihood that they will be miscible with each other. Therefore even though the primary references cited above do not describe selecting polymers based upon their solubility parameters the guidance to select polymers to be miscible based upon solubility parameters was well known at the time of applicants claimed invention. As described in the previous office action one of ordinary skill in the art would have been motivated to find the solubility parameters of the polymers found within Hossainey, Whitbourne or Slrhan in order to calculate which polymers are likely to form blends when mixed together.

Claims 89,91,93-97,99,101-103,134-138 and 140-141,143,145,147-150 are rejected under 35 U.S.C. 103(a) as being unpatentable over Atala (US 6,576,019 B1), in view of Van Krevelen, Properties of Polymers, Chapter 7, 3<sup>rd</sup> ed, for the reasons set forth in the previous office action filed 09/11/2008.

Atala is disclosed above. The Atala patent is silent on the solubility parameter value of the biocompatible polymeric films and the active agent. van Krevelen is used only for the disclosure found within that it was well known in the art at the time of applicants claimed invention that two substances with similar solubility properties should be mutually soluble whereas when the difference between the solubility parameters

Art Unit: 1618

increases the tendency towards dissolution decreases. See page 201 lines 1-15. Even though Atala is silent on the solubility parameters of the polymers and active agents and using the parameters to select the polymers and actives that would be miscible with each other, from the disclosure of van Krevelin it was well known in the art that the difference between solubility parameters could be used to predict solubility and therefore also the miscibility of two substances. Since Atala discloses the use of polymer blends but does not describe any method for predicting which polymers would be miscible with each other one of ordinary skill in the art could have used solubility parameters in a table as disclosed within van Krevelen and had a reasonable expectation of success in blending two polymers if their solubility parameters were relatively close. One of ordinary skill in the art would have been motivated to find the solubility parameters of the polymers found within Atala in order to calculate which polymers are likely to form blends when mixed together.

Claims 89,91,93-97,99,101-103,134-138 and 140-141,143,145,147-150 are rejected under 35 U.S.C. 103(a) as being unpatentable over Atala (US 6,576,019 B1), in view of in view of Coleman et al., Specific interactions and the miscibility of polymer blends, Ch 2, a practical guide to polymer miscibility pages 49-156.

The Atala patent is silent on the solubility parameter value of the biocompatible polymeric films and the active agent. Coleman is used for the review found throughout chapter 2 on predicting polymer miscibility, while the review of Coleman is far too thorough to detail every aspect of predicting miscibility of polymer blends the reference basically states that the closer two polymers are in their solubility parameter the greater

Art Unit: 1618

the likelihood that they will be miscible with each other. In fact Coleman discusses a computer program one can use that predicts the solubility parameters of two polymers and can predict, with some degree of accuracy whether the polymers would be miscible. Even though Atala is silent on the solubility parameters of the polymers and active agents and using the parameters to select the polymers and actives that would be miscible with each other, from the disclosure of Coleman it was well known in the art that the difference between solubility parameters could be used to predict solubility and therefore also the miscibility of two substances. Since Atala discloses the use of polymer blends but does not describe any method for predicting which polymers would be miscible with each other one of ordinary skill in the art could have used solubility parameters or a program as disclosed within Coleman and had a reasonable expectation of success in blending two polymers if their solubility parameters were relatively close, especially if the program predicted the polymer would be miscible. One of ordinary skill in the art would have been motivated to find the solubility parameters of the polymers found within Atala in order to calculate which polymers are likely to form blends when mixed together.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JAMES W. ROGERS whose telephone number is (571)272-7838. The examiner can normally be reached on 9:30-6:00.



Art Unit: 1618

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Michael G. Hartley/

Supervisory Patent Examiner, Art Unit 1618